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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

February 16, 2000

WARNING LETTER NYK 2000-34

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carolyn Raia, M.D., Supervising Radiologist
Seaview Radiology, P.C.
256 Mason Avenue
Staten Island, New York 10305

RE: Facility ID Number 135632

Dear Dr. Raia:

Your facility was inspected on February 7, 2000 by a representative of the New York City Bureau of Radiological Health acting in behalf of the Food and Drug Administration. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- *The medical physicist [REDACTED] did not have a Masters degree or higher in a physical science, with 20 semester hours in physics.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- *There is no written procedure for handling consumer complaints.*
- *The time period between the previous and current surveys for all [REDACTED] of your [REDACTED] x-ray units exceeds 14 months.*
- *The radiologic technologists [REDACTED] and [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.*
- *One of ten reports reviewed at random did not contain an assessment category. It appears that the "Incomplete" category is not used when applicable.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

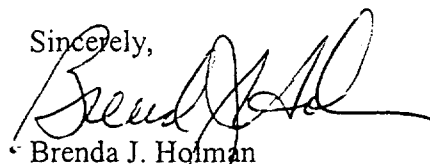
- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any questions about mammography facility requirements, you may contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Hoffman
District Director